**UNITED STATES DISTRICT COURT**
**EASTERN DISTRICT OF MICHIGAN**
**SOUTHERN DIVISION**

HEATHER ALBRECHT and
AARON ALBRECHT,

Plaintiffs,

v.

Case No. 12-11429
Hon. Gerald E. Rosen

FORT DODGE ANIMAL HEALTH, INC.
and PFIZER CORPORATION,

Defendants.
_____/

**OPINION AND ORDER GRANTING**
**DEFENDANTS' MOTION TO DISMISS COMPLAINT**

At a session of said Court, held in
the U.S. Courthouse, Detroit, Michigan
on March 6, 2013

PRESENT: Honorable Gerald E. Rosen
Chief Judge, United States District Court

## I. INTRODUCTION

Plaintiffs Heather and Aaron Albrecht commenced this suit in this Court on March 29, 2012, asserting state-law product liability claims against Defendants Fort Dodge Animal Health, Inc. and Pfizer Corporation, two pharmaceutical manufacturers allegedly involved in the manufacture and sale of ProHeart 6, an injectable, sustained-release heartworm preventative for dogs. In support of these claims, Plaintiffs allege that their veterinarian injected their two dogs with ProHeart 6 during a routine checkup in March of 2009, and that the dogs suffered adverse reactions that will require a specialized diet and

medication for the remainder of their lives. This Court's subject matter jurisdiction rests upon diversity of citizenship, as Plaintiffs are Michigan residents and Defendants are Delaware corporations with their principal places of business in New York and Pennsylvania. *See* 28 U.S.C. § 1332(a).

In lieu of answering the complaint, Defendants have filed a motion under Fed. R. Civ. P. 12(b)(6) seeking the dismissal of Plaintiffs' complaint in its entirety.[1] As Defendants observe, Plaintiffs' product liability claims in this diversity suit are governed by Michigan law. In a 1995 enactment, the Michigan legislature conferred broad immunity upon drug manufacturers and sellers in product liability suits, shielding them from liability, with certain limited exceptions, if the drug in question "was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller." Mich. Comp. Laws § 600.2946(5). In support of the present motion, Defendants argue that Plaintiffs' product liability claims in this action are defeated by the immunity granted under this Michigan statute, where the ProHeart 6 medication giving rise to Plaintiffs' claims purportedly had been approved by the federal Food and Drug Administration ("FDA") at the time this medication was administered to Plaintiffs' dogs. In response, Plaintiffs

[1]Defendants submit in their motion that only Defendant Pfizer, and not Defendant Fort Dodge Animal Health, has been properly served with the complaint. Accordingly, Defendant Fort Dodge states that it is making only a special appearance in order to join in the motion to dismiss.

contend that the immunity conferred by the Michigan statute is unavailable to Defendants here, in light of the recall of ProHeart 6 from the market in 2004 and the express limits to the FDA's subsequent re-approval of this drug.

Defendants' motion has been fully briefed by the parties. Having reviewed the parties' submissions in support of and in opposition to this motion, as well as the remainder of the record, the Court finds that the relevant allegations, facts, and legal arguments are adequately presented in these written materials, and that oral argument would not significantly aid the decisional process. Accordingly, the Court will decide Defendants' motion on the briefs and without a hearing. *See* Local Rule 7.1(f)(2), U.S. District Court, Eastern District of Michigan. For the reasons set forth below, the Court finds that Defendants' motion to dismiss should be granted.

## II. ANALYSIS

### A. The Standards Governing Defendants' Motion

Through their present motion, Defendants seek the dismissal of Plaintiffs' complaint under Fed. R. Civ. P. 12(b)(6) for failure to state a claim upon which relief can be granted. When considering a motion brought under Rule 12(b)(6), the Court must construe the complaint in a light most favorable to the plaintiff and accept all well-pled factual allegations as true. *League of United Latin American Citizens v. Bredesen*, 500 F.3d 523, 527 (6th Cir. 2007). Yet, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S. Ct. 1937, 1949 (2009).

Moreover, "[w]hile a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555, 127 S. Ct. 1955, 1964-65 (2007) (internal quotation marks, alteration, and citations omitted). Rather, to withstand a motion to dismiss, the complaint's factual allegations, accepted as true, "must be enough to raise a right to relief above the speculative level," and to "state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 555, 570, 127 S. Ct. at 1965, 1974. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678, 129 S. Ct. at 1949.

**B. Michigan's Product Liability Statute Bars Plaintiffs' Claims as a Matter of Law.**

In their complaint in this case, Plaintiffs allege that the Defendant drug manufacturers breached a duty owed to Plaintiffs to properly manufacture and test their ProHeart 6 product, and that Defendants also breached implied warranties of fitness and merchantability in their manufacture and sale of the ProHeart 6 medication. Through the present motion, Defendants argue that these product liability theories of recovery are foreclosed by a Michigan statute, Mich. Comp. Laws § 600.2946(5), which accords conclusive weight to the FDA's approval of a drug and its labeling. As discussed below,

the Court agrees.

All are agreed that Michigan law governs this diversity action. Accordingly, the Defendant drug manufacturers may avail themselves of a provision in Michigan's product liability statute that confers broad immunity upon pharmaceutical companies in product liability suits, so long as the drug at issue has been approved for sale by the FDA:

> In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller. However, this subsection does not apply to a drug that is sold in the United States after the effective date of an order of the United States food and drug administration to remove the drug from the market or to withdraw its approval. This subsection does not apply if the defendant at any time before the event that allegedly caused the injury does any of the following:
>
> > (a) Intentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act, . . . and the drug would not have been approved or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted.
> >
> > (b) Makes an illegal payment to an official or employee of the United States food and drug administration for the purpose of securing or maintaining approval of the drug.

Mich. Comp. Laws § 600.2946(5) (citations omitted).

A few years ago, this Court had occasion to consider the reach of this statutory immunity. *See Zammit v. Shire US, Inc.*, 415 F. Supp.2d 760 (E.D. Mich. 2006). The

Court explained:

> As the Michigan Supreme Court has observed, a predecessor statute "provided that evidence showing compliance with governmental or industry standards was admissible in a products liability action in determining if the standard of care had been met." *Taylor v. SmithKline Beecham Corp.*, 468 Mich. 1, 658 N.W.2d 127, 130 (2003) (citations omitted). The above-cited 1995 enactment "went one step further," however, "and provided that compliance with federal governmental standards (established by the FDA) is conclusive on the issue of due care for drugs." *Taylor*, 658 N.W.2d at 130.

*Zammit*, 415 F. Supp.2d at 765.

It is undisputed that most of the statutory criteria for drug manufacturer immunity are satisfied here. First, Defendants observe, and Plaintiffs do not dispute, that ProHeart 6 is a "drug" within the meaning of Michigan's product liability statute. Next, it is clear — and, again, Plaintiffs do not dispute — that this suit qualifies as a "product liability action against a manufacturer or seller" under § 600.2946(5), in light of the product liability theories of recovery asserted in Plaintiffs' complaint. Moreover, Plaintiffs generally do not take issue — with one exception, discussed below — with the proposition that ProHeart 6 has been "approved for safety and efficacy by the United States food and drug administration." Mich. Comp. Laws § 600.2946(5).[2] Finally,

[2]In an effort to demonstrate this FDA approval, Defendants have produced a copy of a page from the FDA's website reflecting the agency's approval of ProHeart in May of 1997. (*See* Defendants' Motion, Ex. A.1.) This web page, unfortunately, addresses the tablet form of ProHeart, and not the injectable, sustained-release version of this drug (ProHeart 6) that was administered to Plaintiffs' dogs. Nonetheless, the Court was able to confirm that the FDA approved Proheart 6 in June of 2001, as this action was embodied in a final agency rule published in the Federal Register. *See* 66 Fed. Reg. 35,756 (July 9, 2001). Although this approval is not part of the pleadings in this case, the Court may take judicial notice of this agency action under Fed. R. Evid. 201. *See, e.g., Kitty Hawk Aircargo, Inc. v. Chao*, 418 F.3d

Plaintiffs do not contend that they can produce the requisite federal findings of bribery or fraud on the FDA that would trigger one of the two statutory exceptions to immunity set forth in § 600.2946(5)(a) and (b). *See Zammit*, 415 F. Supp.2d at 767-68 (explaining that these two exceptions may be triggered only by federal findings of fraud on the FDA or bribery).

Instead, Plaintiffs' sole challenge to the availability of statutory immunity here rests on language in the product liability statute that withdraws this immunity if the drug at issue in a product liability suit was "sold in the United States after the effective date of an order of the United States food and drug administration to remove the drug from the market or to withdraw its approval." Mich. Comp. Laws § 600.2946(5). In Plaintiffs' view, the FDA "withdrew its approval from ProHeart [6] in 2004 and has yet to fully reinstate it." (Plaintiffs' Response Br. at 2.) Plaintiffs argue that this "limited" approval is insufficient to confer immunity under the Michigan product liability statute.

Defendants offer two responses to this challenge. First, they contend that the FDA has neither ordered the removal of Pro Heart 6 from the market nor withdrawn its approval of this drug. In support of their assertion that the FDA "withdrew its approval" of ProHeart 6 in 2004, Plaintiffs point to a page on the FDA website stating that "[p]er FDA's request, the manufacturer of the heartworm medication ProHeart6 agreed in

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453, 457 & n.9 (5th Cir. 2005) (taking judicial notice of a federal agency approval that was "published in the official administrative agency reporter [and] is available on the agency's website and on Lexis and Westlaw").

September 2004 to cease production immediately and recall the drug from the market until FDA's concern about adverse reaction reports associated with the product could be resolved." (Defendants' Reply, Ex. 2, printout of FDA web page referenced in Plaintiffs' response brief.)[3] Defendants argue that the voluntary recall of ProHeart 6 from the market in response to an FDA request does not qualify as either an FDA "order . . . to remove the drug from the market" or an FDA "withdraw[al] [of] its approval," § 600.2946(5), as necessary to overcome the statutory grant of immunity for drugs approved by the FDA.

The Court need not resolve this question, because it agrees with Defendants that the FDA's action in 2004 has been rendered moot in light of subsequent developments occurring before ProHeart 6 was administered to Plaintiffs' dogs in March of 2009. After ProHeart 6 was recalled from the market at the FDA's request, the FDA gave its approval in May of 2008 to a supplemental drug application for ProHeart 6 submitted by Defendant Fort Dodge Animal Health. *See* 73 Fed. Reg. 32,586 (June 9, 2008).[4] As stated in the notice of this FDA approval, this supplemental application "updates the

[3]As Defendants observe, the FDA web page at issue is part of a summary of the FDA's budget for fiscal year 2006. It is not clear that this would be a sufficiently accurate and reliable report of agency action for the Court to take judicial notice of it under Fed. R. Evid. 201. Nonetheless, the Court assumes, for present purposes, that this statement of the FDA's action in 2004 is accurate, because the truth of this statement turns out to be immaterial to the Court's disposition of Defendants' motion.

[4]Again, because the Court has been able to confirm this agency action through a notice filed in the Federal Register, it takes judicial notice under Fed. R. Evid. 201 of this FDA approval.

warning, precaution, adverse reactions, and post-approval experience sections of [the] product labeling" for Pro Heart 6. *Id.* Defendants have produced a copy of the revised August 2008 label for ProHeart 6 that was approved by the FDA in connection with this supplemental application, (*see* Defendants' Motion, Ex. B), and Plaintiffs offer no basis for disputing that this label was in place when ProHeart 6 was prescribed for Plaintiffs' dogs in March of 2009.

While Plaintiffs acknowledge this 2008 FDA approval in their response to Defendants' motion, they suggest that the "limited distribution" allowed under this 2008 approval falls short of the "complete[] reinstate[ment]" that is necessary, in their view, to trigger drug manufacturer immunity under Michigan's product liability statute. (Plaintiffs' Response Br. at 3.) In particular, Plaintiffs point to the FDA's statement, in connection with the agency's 2008 approval of the supplemental drug application for ProHeart 6, that it "concur[red] with Fort Dodge Animal Health's decision to market ProHeart 6 under a risk minimization and restricted distribution plan." (Defendants' Reply, Ex. 3, FDA Veterinarian March/April 2008 Newsletter, "FDA Announces ProHeart 6 Return to Market" (available at http://www.fda.gov/AnimalVeterinary/NewsEvents/FDAVeterinarianNewsletter/ucm084110.htm).) Under this restricted distribution plan for ProHeart 6, "[o]nly veterinarians who have undergone in-depth training from Fort Dodge Animal Health will be allowed to obtain the drug, which will be available only from the sponsor." (*Id.*) Plaintiffs argue that this reflects only a limited, conditional FDA approval of ProHeart 6, as opposed to

the full "approval to release the drug on the open market" that purportedly is required to secure drug manufacturer immunity under § 600.2946(5). (Plaintiffs' Response Br. at 3.)[5]

Plaintiffs' contention on this point, however, is defeated by the plain language of the Michigan product liability statute. Under this statute, a drug manufacturer is entitled to immunity so long as the drug in question "was approved for safety and efficacy by the United States food and drug administration." Mich. Comp. Laws § 600.2946(5). This language draws no distinction between "limited" and "full" approval, but simply requires FDA approval for sale. There is no dispute that ProHeart 6 was given this approval in May of 2008, and that this approval remained in effect when the drug was prescribed for Plaintiffs' dogs in March of 2009.

To the extent that the statute arguably contemplates any conditions to this FDA approval, it provides that immunity is available as to an FDA-approved drug so long as "the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller." Mich. Comp. Laws § 600.2946(5). Even assuming, then, that the restricted distribution plan implemented by Defendant Fort Dodge Animal Health in 2008, with the FDA's concurrence, constituted an essential element of the FDA's approval of ProHeart 6, Plaintiffs fail to suggest any basis for concluding that the doses of ProHeart 6 administered to their dog were not "in compliance" with this distribution plan at the time

[5]As Defendants observe, the significance Plaintiffs mean to give to the phrase "open market" is unclear, as ProHeart 6 is available only by prescription from a licensed veterinarian.

these drugs left Defendants' control. Plaintiffs do not contend, for example, that the veterinarian who prescribed ProHeart 6 for their dog lacked the required training from Fort Dodge Animal Health to be allowed to obtain the drug, or that the doses administered to their dogs were obtained from a source other than Fort Dodge Animal Health.

Accordingly, to the extent that Defendants' restricted distribution plan might be viewed as part and parcel of the FDA's approval of ProHeart 6, Plaintiffs have not called into question Defendants' compliance with this aspect of the agency's approval. It follows that Defendants have established as a matter of law the prerequisites for immunity set forth in § 600.2946(5) — namely, that ProHeart 6 was "approved for safety and efficacy" by the FDA at the time this drug was administered to Plaintiffs' dogs, and that "the drug and its labeling were in compliance with" this FDA approval at the time the drug left Defendants' control.[6]

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[6]When this Court grants a motion to dismiss a complaint, its usual practice is to give the plaintiff an opportunity to file an amended complaint that cures the deficiencies identified in the plaintiff's initial pleading. This practice need not be followed, however, if the resulting amended complaint "could not withstand a Rule 12(b)(6) motion to dismiss." *Rose v. Hartford Underwriters Insurance Co.*, 203 F.3d 417, 420 (6th Cir. 2000). In this case, Defendants have argued that "[t]he defects in the complaint cannot be cured by an amendment," (Defendants' Motion, Br. in Support at 8), and Plaintiffs fail to contend otherwise in their response to Defendants' motion. Neither did Plaintiffs take advantage of their opportunity under Fed. R. Civ. P. 15(a)(1)(B) to amend their complaint as a matter of course within 21 days after service of Defendants' motion. Finally, and more generally, Plaintiffs do not suggest that they would be able to put forward allegations that would overcome Defendants' immunity under Michigan's product liability statute — *e.g.*, that the ProHeart 6 doses supplied to their veterinarian and administered to their dogs failed to comply in some respect with the terms of the FDA's approval. Under these circumstances, the Court agrees with Defendants that leave to amend need not be granted.

## III. CONCLUSION

For the reasons set forth above,

NOW, THEREFORE, IT IS HEREBY ORDERED that Defendants' May 21, 2012 motion to dismiss Plaintiffs' complaint (docket #6) is GRANTED.

s/Gerald E. Rosen
Chief Judge, United States District Court

Dated: March 6, 2013

I hereby certify that a copy of the foregoing document was served upon the parties and/or counsel of record on March 6, 2013, by electronic and/or ordinary mail.

s/Julie Owens
Case Manager